In the Supreme Court

Appeal from the Court of Appeals Presiding Judge Jessica R. Cooper

ANTONIO CRAIG, by his Next Friend, KIMBERLY CRAIG,

Plaintiff-Appellee,

Docket No. 121419

 \mathbf{v}

Court of Appeals No. 206951

OAKWOOD HOSPITAL,

Defendant-Appellant,

Wayne County Circuit Court Case No. 94-410338-NH Honorable Carole Youngblood

and

HENRY FORD HOSPITAL d/b/a HENRY FORD HEALTH SYSTEM, ASSOCIATED PHYSICIANS, P.C., ELIAS G. GENNAOUI, M.D., and AJIT KITTUR, M.D.,

Defendants.

BRIEF ON APPEAL OF DEFENDANT-APPELLANT OAKWOOD HOSPITAL

ORAL ARGUMENT REQUESTED

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STATEMENT OF BASIS OF JURISDICTION

This Court has jurisdiction in this matter pursuant to its September 12, 2003 Order granting Defendant-Appellant Oakwood Hospital's Application for Leave to Appeal from the February 1, 2002 decision by the Court of Appeals which affirmed in all material respects the July 10, 1997 judgment entered in Plaintiff's favor. MCR 7.302(F).

The Court's Order states as follows:

On order of the Court, the application for leave to appeal the February 1, 2002 decision of the Court of Appeals and the motions for leave to file briefs amici curiae and for pro hac vice admission are considered. The motions to file briefs amici curiae are GRANTED. The motion for pro hac vice admission of Mark A. Stinnett and Philipa M. Remington is GRANTED. The application for leave to appeal is GRANTED, limited to the following issues: (1) Whether the witnesses' testimony was based on facts not in evidence and whether the trial court erred in permitting the testimony of plaintiff's expert witnesses. See People v Young, 418 Mich 1, 21, n 7 (1983). (2) Whether the trial court erred in finding defendant Henry Ford Hospital liable on a successor liability theory. In all other respects, the application for leave to appeal is DENIED. We further ORDER that this case be argued and submitted to the Court together with the cases of Craig v Oakwood Hospital (Docket Nos. 121405, 121407-09) at such future session of the Court as all cases are ready for submission.

STATEMENT OF QUESTIONS PRESENTED

I. "Whether [Plaintiff's] witnesses' testimony was based on facts not in evidence"?

The trial court answered: The trial court did not address

this question.

The Court of Appeals answered: No.

Oakwood answers: Yes.

II. "Whether the trial court [and Court of Appeals] erred in permitting the testimony of Plaintiff's expert witnesses"?

The trial court answered: No.

The Court of Appeals answered: No.

Oakwood answers: Yes.

I. INTRODUCTION

Plaintiff, Antonio Craig, suffers from cerebral palsy; he was diagnosed with the condition at three months of age, the first time he showed symptoms of a neurological abnormality. Fourteen years later, he filed this medical malpractice action against Defendants, claiming that they are to blame for his condition. The medical records of what took place when Plaintiff was born at Oakwood Hospital in 1980 describe a normal labor and delivery of a healthy baby. Plaintiff's two experts — an obstetrician and a pediatric neurologist — offered a theory of how Plaintiff Antonio Craig might have sustained an injury to his brain during the labor that cannot be reconciled with the established record facts and that is not even recognized by medical science as anatomically possible, much less supported by the body of knowledge in their respective specialized fields. In disregard or defiance of the established factual record, Plaintiff's experts theorized that Plaintiff's mother received an overdose of Pitocin during labor, inducing severe uterine contractions which injured Plaintiff's brain by the traumatic impact of his head "pounding" and "grinding" into an unspecified part of the pelvic anatomy.

Following a jury verdict of \$35 million in Plaintiff's favor, Defendants moved for JNOV, the gist of which was that Plaintiff's experts invented factual premises to fit a theory of causation that lacks independent, objective validation in medical science, finds no support in the established factual record, and is actually in conflict with the established record evidence. The trial court denied Defendants' requested relief and entered a \$20 million judgment. In disregard of longstanding legal authorities, the Court of Appeals, in a published opinion authored by Judge Jessica R. Cooper, affirmed the jury's verdict based on Plaintiff's experts' testimony. 2

The verdict was reduced by the trial court in accordance with applicable statutory adjustments.

The other members of the panel, Judges Sawyer and Owens, remitted Plaintiff's claim for loss of wage earning capacity from \$1,992,138 to \$967,045 but otherwise concurred.

Neither the trial court nor the Court of Appeals discharged their mandatory and fundamentally important judicial responsibility to evaluate whether an expert's causation theory is reliable and well-founded in his specialized field and substantially supported by the admissible facts of the case. The direct consequence of failing to discharge this fundamental judicial responsibility was a verdict based on the unabashed speculation of expert advocates.

Because experts are presented to juries as having specialized knowledge, skill and authority, their communications to a jury are especially influential even though expert witnesses routinely have no personal knowledge of the facts. This is why trial courts must exercise their gate-keeping responsibility to ensure that expert witnesses are not used to fill a factual void, or worse, to present a persuasive theory of what took place that disregards or even distorts the established factual evidence. The testimony of experts engaged to interpret the facts and present a theory of causation to a jury should prompt trial courts to be especially vigilant about exercising this responsibility because the ultimate result of an expert's presentation of an unfounded theory of causation is that the jury will accept it uncritically and base their verdict upon it. This is just what happened here.

Before the trial ever began, the evidence adduced through discovery revealed the lack of objective, independent validation for Plaintiff's causation theory as to how Antonio Craig sustained brain injury. If the trial court had conducted the requisite <u>Davis-Frye/MRE</u> 702³ hearing for which Defendants moved, the lack of a legally sufficient foundation for Plaintiff's

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People v Davis, 343 Mich 340; 72 NW2d 269 (1955); Frye v United States, 293 F 1013 (CA DC, 1923). See also People v Young, 418 Mich 1, 21 n 7; 340 NW2d 805 (1983), specifically referenced in this Court's order granting leave, in which the Court made clear that the burden of establishing the reliability, and thus the admissibility, of expert testimony rests with the proponent of the expert opinion – in this case, Plaintiff.

causation theory would have been exposed.⁴ Based on these legal authorities, the trial court was obligated to conduct such a hearing once the court was presented with a motion challenging Plaintiff's experts' causation theory and with the sworn testimony of Plaintiff's expert pediatric neurologist, Dr. Ronald Gabriel, confirming the lack of any independent validation in medical science for this "pounding and grinding" theory of fetal brain injury. A <u>Davis-Frye/MRE</u> 702 hearing would have revealed that Plaintiff's causation theory is not even recognized as anatomically possible in any specialized field of medical science and that the theory materially conflicts with the established factual record.

The fundamental gatekeeping responsibility that trial courts must discharge before expert testimony may be properly presented to a jury requires a **two-prong** analysis: (1) a determination of whether the expert's testimony is independently validated and reliable based on the body of knowledge in the expert's specialized field; and (2) a determination of whether the expert's testimony is supported by the factual evidence in the particular case — whether, in the words of the United States Supreme Court in <u>Daubert v Merrell Dow Pharmaceuticals, Inc.</u>, 509 US 579; 113 S Ct 2786; 125 L Ed 2d 469 (1993), there is a sufficient "fit" between the expert's testimony and the facts of the case. In Michigan, this two-prong analysis derives from the principles for determining the reliability of expert testimony presented in Michigan's <u>Davis-Frye</u> authorities, in MRE 702, and in the other longstanding Michigan case authorities cited *infra* which, together with MRE 703, require that expert testimony be substantially supported by the factual record — that there be substantial "fit" between the expert's testimony and the record facts.

⁴ This case arose prior to the Legislature's enactment of MCL 600.2955, as well as this Court's recent amendments of MRE 702 and 703. However, as explained fully, <u>infra</u>, the trial court's gatekeeping responsibility is the same under all of these standards, the application of any of which mandates JNOV in Defendants' favor.

This is the same two-prong analysis that is followed by the federal courts in accordance with Daubert.⁵

Without the necessity of a protracted journey through every detail of the pretrial record, a Davis-Frye/MRE 702 hearing would have exposed the lack of any independent validation or factual basis to support the essential inference that, more likely than not, Plaintiff suffered brain injury in accordance with Plaintiff's experts' causation testimony. When Defendants filed their motion for a Davis-Frye/MRE 702 hearing, the admissible factual record was sufficiently developed to expose the lack of "fit" between Plaintiff's experts' testimony and the facts of the case. In this case, both Dr. Gabriel's and Dr. Gatewood's testimony fails to meet the second "prong" of the gatekeeping analysis. The testimony of both of these experts not only lacks the requisite substantial factual support in the admissible record evidence – the requisite "fit" with the facts – but these experts' opinions disregard and even contradict the record facts. The distance between Plaintiff's experts' testimony and the factual record only widened over the course of a five-week trial, further confirming that this testimony was, at best, unreliable speculation unsuitable for jury consideration.

Plaintiff's causation theory was exclusively the invention of his experts, was not based on a reliable foundation in medical science or the record facts, and should never have been presented to a jury. If the trial court had discharged its mandatory gatekeeping responsibility before trial, during the trial, or, at the very latest, when post-verdict motions were presented, it would have found Plaintiff's experts' testimony to be unreliable, unsupported by record facts, and

See Nelson v Tennessee Gas Pipeline Co, 243 F3d 244, 250 n 4 (CA 6, 2001) (explaining that <u>Daubert</u> requires an "assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue"); <u>Grimes v Hoffman-LaRoche, Inc</u>, 907 F Supp 33, 35 (DC NH 1995) (the "fit" requirement of <u>Daubert</u> "refers to the necessity of a connection between the expert's testimony and the facts of the case").

insufficient as a matter of law to sustain a prima facie case. An opinion from this Court directing judgment NOV in favor of Defendants would be the belated, but just, disposition of this case and would offer the trial courts and litigants in cases generally much-needed guidance as to the fundamental, mandatory gatekeeping responsibility of the judiciary.⁶

II. STATEMENT OF FACTS AND PROCEDURAL BACKGROUND

A. The Labor and Delivery

Kimberly Craig was admitted to Oakwood Hospital on July 16, 1980, at 6:00 a.m. She had experienced a rupture of the membranes at 5:30 a.m., but uterine contractions had not begun. (358a; Nurses Notes [83a]); Labor Record [84a]; Admission Notes [85a]). Defendant Ajit Kittur, M.D., who had provided prenatal care to Ms. Craig, ordered that an external monitor be placed around her abdomen in order to record the fetal heartbeat and the duration and number of contractions. (266a-267a). As Plaintiff's obstetrical expert, Dr. Gatewood, acknowledged, an external monitor cannot alone measure the strength of contractions (e.g., "mild," "moderate," "severe") (Dr. Gatewood: 502a, 224a-225a; Dr. Gabriel: 253a-254a, 259a; Dr. Elias Gennaoui: 269a, 294a-295a; Dr. Mitchell Dombrowski: 327a-328a, 342a-343a; Nurse Rhea Hill: 351a-352a; Nurse Jill Paslaiko: 399a). As Dr. Gatewood also agreed, the strength of contractions were instead appropriately determined by the nurses' palpation of the mother's abdomen by which they can feel the strength of the contraction. (Dr. Gatewood: 224a-225a, ; Dr. Dombrowski: 342a-343a; Nurse Hill: 352a-353a, 356a-357a; Nurse Paslaiko, 383a).

Since its publication in February 2002, the Court of Appeals' opinion has been regularly presented to trial courts as controlling authority relieving judges of the obligation to conduct a Davis-Frye/MRE 702 hearing whenever the litigant challenging the reliability of expert testimony fails *to prove* that the testimony is based on "novel" scientific evidence. (See, e.g., orders denying defense requests for Davis/Frye/MRE 702 hearings in Kimberly Cole v Annapolis Hospital et al., Wayne Circuit Court No. 01-100211-NH), and McCarthy v Henry Ford Health System et al., Oakland Circuit Court No. 01-031400-NH (130a)).

Dr. Kittur ordered an intravenous (IV) KO "keep open" fluid line for the purpose of keeping Ms. Craig hydrated and to provide a mechanism for administering medication if necessary. (Doctor's Orders [87a]; 278a-280a; 335a). Pursuant to Dr. Kittur's order, 1000cc of 5% Ringers lactate solution began to be administered to Ms. Craig at 10:00 a.m. (83a; 262a).

At 11:30 a.m., Ms. Craig was examined by Defendant obstetrician Elias Gennaoui, M.D. (263a-265a; Summary of Dr. Gennaoui [88a]). Because Ms. Craig's membranes had been ruptured for six hours, exposing her and the unborn baby to possibly life-threatening infection if the baby was not delivered relatively soon, Dr. Gennaoui decided to administer the medication Pitocin which was and still is commonly used to induce contractions. (263a, 282a, 329a). Accordingly, Dr. Gennaoui wrote an order for 10 units (1 amp) of Pitocin (Doctor's Orders [87a]). The initial dosage of Pitocin administered was 2 milliunits (mu), and was increased in 2 mu increments progressively throughout the day. (Intravenous Induction Record [89a]). As Plaintiff's obstetrical expert, Dr. Gatewood, also acknowledged, this dosage plan, as reflected in the medical records, was appropriate (222a).

From 11:30 a.m. to the time that Pitocin was discontinued at 6:00 p.m., Ms. Craig's contractions were monitored at least thirteen times by the doctors and nurses who palpated her abdomen. During that time, as Plaintiff's own expert acknowledged, Ms. Craig's contractions were recorded in the chart as ranging from "mild" to "moderate" and not out of the ordinary (Nurses Notes [83a]; Labor Record [84a]; Summary of Dr. Gennaoui [88a]; IV Induction Record [89a]; Dr. Gatewood: 458a-501a; Dr. Bernal: 299a-303a; 310a; Nurse Geraldine Schmidt: 372a; Nurse Jill Paslaiko: 377a-399a). Thus, the medical records do not describe any contractions throughout the entire labor that were any stronger than "moderate."

At 6:45 p.m., Ms. Craig was taken to the delivery room where Plaintiff was born at 6:51 p.m. by normal, spontaneous delivery. (Summary of Dr. Gennaoui [88a]; 173a-174a). Dr.

Gennaoui immediately examined Plaintiff and noted "apparently normal newborn." (274a-276a). Plaintiff's APGAR scores – which measure such functions as heart rate, respiration, tone, reflexes, and skin color at 1 and 5 minutes after birth – were 9 and 10 (respectively) out of 10. (354a-355a). In the nursery, Plaintiff exhibited all of the signs of a normal, healthy newborn. (Newborn Nursery Record [92a]; Dr. Dombrowski, 323a-324a, 330a-334a; Dr. Steven Donn: 426a, 438a-440a).

On July 18, 1980, Plaintiff was examined by Carolyn Johnson, M.D., a pediatrician (Oakwood Hospital Admission and Progress Notes [85a]; 325a-326a). Her examination indicated that Plaintiff's mental status was alert and active and that his pupils were equally reactive, round, and reacting to light, a normal neurological finding. (Admission and Progress Notes [85a]; 333a-334a; 439a). Plaintiff also exhibited normal neonatal reflexes. (Admission and Progress Notes [85a]; 439a-440a). Overall, Dr. Johnson found Plaintiff to be a "well term male newborn." (Admission and Progress Notes [85a]; 334a; 440a).

B. Post-Discharge

According to Ms. Craig, the first indication of any abnormality in Plaintiff was at the age of three months, when she noticed that he was not reaching for objects. (Children's Hospital Discharge Summary [93a]). Pediatrician Dr. Johnson examined Antonio and noted that Plaintiff was developmentally delayed, and might possibly suffer from spasms. (Id.). She referred Plaintiff to Children's Hospital of Michigan for further evaluation. Plaintiff was admitted to Children's Hospital on June 2, 1981, and was evaluated by Dr. Michael A. Nigro (Id.; 6/3/81 Consultation Form [96a]), a pediatric neurologist. (405a).

Dr. Nigro reviewed Plaintiff's Oakwood Hospital chart and talked with Ms. Craig about the childbirth. Dr. Nigro's records reflected that Plaintiff had suffered no neonatal distress. (6/3/81 Consultation Form [96a]; 408a). Dr. Nigro's impression was nonprogressive

encephalopathy (nonprogressive brain disorder) with global developmental delay (affecting all areas of development) and with mild spasticity in the extremities (a characteristic of cerebral palsy). (6/3/81 Consultation Form [96a]; 406a-407a). The cause of Antonio's condition was unclear. (407a). Plaintiff was discharged, and was to be seen by Dr. Johnson and by Dr. Nigro for further follow-up.

Dr. Nigro saw Plaintiff again on October 30, 1981. (10/29/81 Dr. Nigro Notes [98a]). His clinical assessment was chronic, nonspecific encephalopathy with retardation, psychomotor delay, cerebral palsy and epilepsy. (<u>Id</u>.). He recommended Phenobarbital, occupational and physical therapy, and consultation with a social service specialist. (<u>Id</u>.)

The last time Dr. Nigro saw Plaintiff was on March 3, 1993 when Plaintiff was 12 years old. His clinical condition was characterized as profound encephalopathy with spastic quadriplegia, mental retardation, and aphasia. (3/8/93 Letter to Ronald Bennett [99a]). The cause of this condition remained "unclear." Dr. Nigro recommended an MRI scan of the brain in an attempt to obtain more information about the possible cause and progression of the condition. As explained <u>infra</u>, the MRI, conducted at Children's Hospital, did not reveal any developmental anomaly or injury in the brain, and did not shed any light on the cause of Antonio's condition.

C. Plaintiff's Causation Theory at Trial

The medical records and the testimony of the doctors and nurses who cared for Ms. Craig describe an uncomplicated labor, with mild to moderate contractions, and the birth of a healthy baby of normal appearance and behavior and with no signs of neurological impairment. However, Plaintiff's experts' offered a theory of what occurred during labor and delivery that is not described in the medical records. **Over repeated defense objections that his testimony was contradicted by the medical records** (see 169a, 179a-187a), Plaintiff's expert obstetrician, Dr. Paul Gatewood, was allowed to testify that Ms. Craig was mistakenly given a **double dose** of

Pitocin (based on an apparent assumption that the Oakwood nurses were confused about who was supposed to be giving Pitocin to Ms. Craig and mistakenly **both** gave her amount of Pitocin ordered by Dr. Gennaoui), and that this massive overdose caused severe, prolonged uterine contractions (in disregard of the medical records describing the contractions as "mild" to "moderate"), resulting in a prolapsed umbilical cord that deprived the baby of sufficient blood flow. However, Dr. Gatewood could not say how this reduction in blood through the cord, which he described as an hypoxic-ischemic episode, actually injured Plaintiff's brain. (See 193a, 209a-210a, 231a).

Instead, Dr. Gatewood deferred to Plaintiff's other expert, Dr. Ronald Gabriel, a pediatric neurologist, as to the causal sequence leading from the hypoxic-ischemic episode to a discrete injury to the brain. (Id.)⁷ Dr. Gabriel, however, rejected Dr. Gatewood's theory that an hypoxic event occurred and offered instead his own theory that the compressive force of severe uterine contractions caused Plaintiff's head to be "pounded" and "ground" into a hard structure in his mother's pelvic anatomy that Dr. Gabriel acknowledged he was not qualified even to identify. (234a-237a, 242a-244a). Dr. Gabriel further admitted that he could not explain the mechanism by which this "pounding" and "grinding" of the fetal head against the pelvic anatomy occurred, because those were "obstetrical questions I'm not competent to answer." (See 242a-244a, 251a-252a, 255a-258a).

Neither before nor during the trial was Dr. Gabriel able to cite any medical or scientific literature confirming that fetal brain injury **can be caused** by the "pounding and grinding" of the fetal head into a hard structure within the mother's pelvic anatomy. Indeed, Plaintiff's expert was

The brain abnormality was revealed for the first time in an MRI performed in 1993, some twelve years after Antonio Craig's birth. Nothing in the report indicates that the brain abnormality was caused during the birthing process and, indeed, given the child's normal, Footnote continued on next page ...

never even able to cite anecdotal reports that such a phenomenon had ever been recorded in the history of medical science. Moreover, all of the obstetricians who testified at trial, **including Plaintiff's own expert, Dr. Gatewood**, rejected the theory that Plaintiff suffered head trauma as a result of contact with any hard structure in the pelvic anatomy (see Dr. Gatewood: 231a; Dr. Gennaoui: 274a, 290a-293a; Dr. Humberto Bernal: 304a-308a, 311a-315a; Dr. Mitchell Dombrowski: 316a-319a). As Dr. Humberto Bernal (a board-certified obstetrician who examined Ms. Craig during her labor) clearly explained, it is impossible for the baby's head to have been traumatized by impact with a hard structure in the pelvic anatomy because the baby is completely surrounded by soft tissue. (306a).

D. Defense Pre-Trial Efforts to Exclude Plaintiff's Causation Testimony

Based upon Dr. Gabriel's earlier deposition testimony, in which he failed to cite any medical or scientific literature to support his "pounding and grinding" theory, Oakwood moved for a pre-trial <u>Davis-Frye/MRE</u> 702 hearing, asking the trial court to evaluate the reliability of this expert testimony. However, the trial court denied the motion, finding that a <u>Davis-Frye/MRE</u> 702 examination was not necessary because Defendants had the burden of establishing the **unreliability** of Plaintiff's experts' causation testimony and because Defendants had not met this burden. (VI, pp 17-20 [2a]). Without regard to the requirement set forth in <u>People v Young</u>, 418 Mich 1, 21 n 7; 340 NW2d 805 (1983) (and other authorities), that the burden of establishing reliability lies with the proponent of the expert testimony, and despite Dr. Gabriel's own admission that he could offer no support for such a causation theory, the trial court denied Oakwood's motion for a Davis-Frye/MRE 702 hearing.

Footnote continued from previous page ...

healthy neurological status at birth (as recorded in the medical records), the evidence militates against any inference that this brain abnormality was sustained at birth.

E. Further Defense Challenges to Plaintiff's Experts' Causation Theory at Trial

Throughout the course of trial, the court was provided with many opportunities to discharge its gatekeeping responsibility and prevent Plaintiff's unfounded expert causation testimony from reaching a jury. Defendants repeatedly objected to Dr. Gatewood's "reinterpretation" of the medical records to support his fantastic theory that Ms. Craig was given a massive overdose of Pitocin that caused severe uterine contractions (see 169a, 179a-187a) – an essential factual assumption on which Plaintiff's causation theory rested. Defendants also moved for a directed verdict based upon the legal insufficiency of Plaintiff's experts' testimony to support a prima facie case. The trial court denied that motion (see 448a-453a; 454a-455a).

After the jury returned a verdict in Plaintiff's favor, Oakwood moved for JNOV on the ground that Plaintiff's case should never have been presented to the jury because it was based on unreliable expert testimony lacking the required foundation in medical science and in the factual record and because Plaintiff's experts' testimony, even taken together, did not describe a complete, logical sequence of cause and effect leading to the alleged brain injury.

The trial court denied the defense motions for JNOV (see Order [50a]; JNOV Hearing Transcript [26a]) despite the fact that both basic anatomy and the established record of Ms. Craig's labor and delivery contradicted the experts' conclusion that Ms. Craig was given a massive overdose of Pitocin, causing severe uterine contractions, and resulting in either hypoxia (according to Dr. Gatewood) or head trauma caused by the traumatic "pounding" and "grinding" (according to Dr. Gabriel, even though Dr. Gabriel acknowledged that he was incompetent to describe the mechanism by which the head trauma and brain injury occurred).

F. The Court of Appeals' Decision

In a published opinion, the Court of Appeals affirmed the jury's verdict in all material respects. In relevant part, the Court of Appeals upheld the trial court's denial of Oakwood's

request for a pre-trial <u>Davis-Frye/MRE 702</u> hearing, as well as its denial of Oakwood's post-trial motion for JNOV. <u>Craig v Oakwood Hospital</u>, 249 Mich App 534; 643 NW2d 580 (2002) [53a]. The Court of Appeals agreed with the trial court that it was Defendants' burden to prove that Plaintiff's experts' causation theory was not sufficiently well-founded to be presented to a jury. Slip op at 3-4. In disregard of this Court's decision in <u>Young</u>, 418 Mich at 21, n 7, and other authorities requiring the proponent of the expert testimony to establish its reliability, the Court of Appeals concluded that Plaintiff's experts' testimony was properly admitted because Defendants failed to prove that the theory was based on "novel" scientific evidence.

In addition, the Court of Appeals rejected Oakwood's challenges to Plaintiff's experts' testimony that neither the scenario offered by Dr. Gabriel, nor that offered by Dr. Gatewood, described a coherent, complete logical causal sequence by which the brain injury was sustained during labor. Slip op at 5-8. As to Oakwood's challenge to both the factual basis for Plaintiff's experts' testimony and Oakwood's challenge to the incompleteness and inconsistency of the experts' causal scenarios, the Court of Appeals found the expert testimony to be admissible because Ms. Craig's treating nurses and physicians "had no independent recollection of the events" of her labor and delivery. According to the Court of Appeals' published opinion, Plaintiff's experts – and indeed all experts – are free to "interpret" medical records to conform to their causation opinions, and any inconsistencies between the experts' opinions and the established facts present only issues of "credibility" and "weight" that may properly be delegated to a jury to sort through. Slip op at 4-5.

This Court subsequently granted Oakwood's Application for Leave to Appeal on September 12, 2003, limited to "[w]hether the witnesses' testimony was based on facts not in evidence and whether the trial court erred in permitting the testimony of plaintiff's expert witnesses. See People v Young, 418 Mich 1, 21 n 7." This case was further ordered to be

submitted along with the substantially identical appeals filed by co-Defendants Henry Ford Hospital, Dr. Elias Gennaoui, and Associated Physicians, P.C.

III. ARGUMENT

A. Standards of Review

At issue in this case is whether the trial court below fulfilled its gatekeeping obligation in addressing Oakwood's challenge to the proposed testimony of Dr. Gabriel, and whether the trial court should have granted Oakwood's motions for a directed verdict and JNOV based upon the lack of substantial factual support for Plaintiff's experts' causation theory and the lack of the requisite support in medical science for such a theory.

The nature and extent of a trial court's responsibility to ensure the reliability of proposed expert testimony presents a question of law. Questions of law are subject to de novo review. Kelly v Builders Square, Inc, 465 Mich 29, 34; 632 NW2d 912 (2001). This Court also reviews de novo the trial court's denial of the defense motions for a directed verdict and for JNOV. This Court must examine the testimony adduced at trial and all legitimate inferences that may be drawn in the light most favorable to the non-moving party. A directed verdict and/or JNOV is appropriate if the evidence so viewed fails to establish a claim as a matter of law. Sniecinski v Blue Cross and Blue Shield of Michigan, 469 Mich 124, 131; 666 NW2d 186 (2003).

B. Not Only Does Plaintiff's Experts' Testimony Lack the Requisite Substantial Support in the Factual Record, Their Testimony is Contrary to the Established Record of What Took Place During Mrs. Craig's Labor and Delivery

The established factual record of what took place during Kimberly Craig's labor and delivery in 1980 is contained in the medical records and the testimony of those nurses and doctors who cared for Ms. Craig. Despite the established medical facts that the labor and delivery proceeded without complication, and that Ms. Craig's uterine contractions were never

more than "moderate," Plaintiff's experts offered the following incomplete and internally inconsistent causation theory to account for Plaintiff's neurological impairment:

- (1) The nurses and doctors negligently gave Ms. Craig a massive dose of the labor-inducing medication, Pitocin, which caused . . .
 - (2) Severe uterine contractions, which resulted in . . .
- (3)(a) Hypoxia and <u>not</u> fetal head trauma (according to Dr. Gatewood, Plaintiff's obstetrical expert).
- (3)(b) Fetal head trauma and <u>not</u> hypoxia (according to Dr. Gabriel, Plaintiff's neurological expert).

Whether examined separately or as pieces of one attempted theory of causation, the opinions of Plaintiff's experts do not even describe a logical sequence of cause and effect that theoretically explains what occurred from the time of the alleged negligence to the time of the alleged brain injury. Further, neither expert's theory finds any factual support in the evidentiary record, much less the required substantial support, for the factual inferences on which they are balanced. For these reasons, Plaintiff's case should never have been presented to a jury.

1. Expert Testimony That is Not Substantially Supported by Evidence in the Established Factual Record May Not be Presented to a Jury

Long-standing authorities of both this Court and the Court of Appeals have consistently characterized expert testimony that is not substantially supported by the established factual record as inadmissible speculation. See, e.g., Howe v Michigan CR Co, 236 Mich 577; 211 NW 111 (1926); Kaminski v Grand Trunk Western R Co, 347 Mich 417; 79 NW2d 899 (1956); Parsonson v Construction Equipment Co, 386 Mich 61; 191 NW2d 465 (1971); Kupkowski v Avis Ford,Inc, 395 Mich 155; 235 NW2d 324 (1975); Jordan v Whiting Corp, 396 Mich 145; 240 NW2d 468 (1976); Holloway v General Motors Corp Chevrolet Division, 403 Mich 614;

271 NW2d 777 (1978); <u>Mulholland</u> v <u>DEC Int'l Corp.</u>, 432 Mich 395; 443 NW2d 340 (1989); <u>Skinner v Square D Co.</u>, 445 Mich 153; 516 NW2d 475 (1994); <u>Jubenville v West End Cartage, Inc.</u>, 163 Mich App 199; 413 NW2d 705 (1987); <u>McCune v Meijer, Inc.</u>, 156 Mich App 561; 402 NW2d 6 (1986); <u>Green v Jerome Duncan Ford</u>, 195 Mich App 493; 491 NW2d 243 (1992); <u>Badalamenti v William Beaumont Hospital</u>, 237 Mich App 278; 602 NW2d 854 (1999).

As these decisions have made clear (which are consistent with the second prong, or "fit" requirement, of the federal Daubert analysis), when the factual record does not allow a rational inference that the expert's proposed sequence of cause and effect probably did occur, the expert should not be permitted to present his theory to a jury. Thus, each causal sequence in the expert's theory must logically explain what occurred from the point of the allegedly negligent act to the point of injury. Additionally, each sequence in the theory must have substantial support in the evidentiary record or it remains theoretical, without "selective application" from the established facts. See Kaminski, 347 Mich at 417. In accordance with the sound principles established in the many Michigan authorities cited above, there is but one test to determine the sufficiency of the record support for expert opinion – one test of the "fit" between expert opinion and the established facts of the case: the judicial gate-keeper must determine whether the established factual record supports the reasonable inference that, more likely than not, each one of the factual assumptions on which the expert's testimony depends is accurate. See Mulholland, 432 Mich 395; Skinner, 445 Mich 153. The lack of substantial evidence in the evidentiary record supporting the factual inferences upon which Plaintiff's experts' testimony is

The unfortunate failure of many trial courts to adhere to this rule is what no doubt led this Court to recently amend MRE 703 to make clear that an expert's testimony **must be based on facts in evidence**. As the Staff Comment to MRE 703 explains: "The modification of MRE 703 corrects a common misreading of the rule by allowing an expert's opinion only if that opinion is based exclusively on evidence that has been introduced into evidence in some way other than through the expert's hearsay testimony."

based exposes these experts' opinions as inadmissible speculation unsuitable for presentation to a jury. This gap between Plaintiff's experts' opinions and the established factual record only grew as these experts were permitted freely to "re-interpret" (to the point of "re-writing") the events documented in detail in the medical records.

Until the Court of Appeals' decision below, this Court and the Court of Appeals had consistently explained and applied the principle that "there must be facts in evidence to support the opinion testimony of an expert. Mulholland, 432 Mich at 411; Skinner, 445 Mich at 160-161. For example, in Skinner, this Court determined that the plaintiffs' expert's testimony that an allegedly defective product was the proximate cause of the death was not admissible evidence supporting the element of causation in fact because the established facts did not permit a jury or an expert to conclude that, more likely than not, the alleged defect caused the death.

Likewise, in <u>Thornhill</u> v <u>Detroit</u>, 142 Mich App 656, 658-661; 369 NW2d 871 (1985), the Court of Appeals held that expert testimony that the decedent "probably died after aspirating his vomitus," was not admissible because there was no evidence in the record supporting the necessary fact that the decedent had vomitus in his mouth during the relevant time period.

And, similarly, in <u>Green</u>, 195 Mich App at 499, the Court of Appeals properly rejected expert testimony that the car accident in which the plaintiff was injured was caused by defective brakes that "locked up" while the vehicle in which the plaintiff was a passenger was nearing the end of a curve in the road because there was no evidence in the record to support this theory. The expert's theory, which required, among other things, the presence of skid marks well into the curve, was inconsistent with the testimony of the fact witnesses that the only skid marks observed were either before the curve or a short distance into it. Noting that the expert's deposition testimony "essentially discounted the fact witnesses' testimony," <u>id</u>. at 496, the Court

of Appeals held that the expert's testimony had to be excluded because the expert was unable to reconcile the inconsistencies between his opinion and the established factual record. Id. at 500.

Consistent with Skinner, Thornhill, Green and the other authorities cited above, and especially instructive here, is the Court of Appeals' decision in Badalamenti v William Beaumont Hospital, 237 Mich App 278; 602 NW2d 854 (1999). In that case, the plaintiff's expert witness testified that the defendants were negligent in failing to diagnose and treat the plaintiff for cardiogenic shock when he was admitted to the hospital for a heart attack. In overturning a jury verdict based on that testimony, the Court of Appeals held that there were material inconsistencies between the theory of the plaintiff's expert and the facts as established by the medical records and the testimony of the witnesses who were present at the time of the plaintiff's treatment. The medical records and the testimony of those with personal knowledge established that the plaintiff's hemodynamic measurements and echocardiograms confirmed normal heart function – a finding that, the plaintiff's expert admitted, was inconsistent with cardiogenic shock.

Id. at 287-288. Because the plaintiff's expert's opinion was "based on assumptions that are not in accord with the established facts," the expert's opinion could not be "substantial, legally sufficient evidence" on which a jury could base a verdict. Id. at 286, 288-289.

Despite the clear import and applicability of <u>Badalamenti</u> and the many other authorities consistent with <u>Badalamenti</u>, the Court of Appeals panel in the present case attempted to distinguish <u>Badalamenti</u> on the following basis: "[i]n this case the eyewitnesses testified that they had no independent recollection of the pertinent events." Slip op at 8. This rationale attempting to distinguish <u>Badalamenti</u> is a plainly erroneous interpretation of the analysis and conclusions of <u>Badalamenti</u> and the other authorities discussed herein. The longstanding precedent of this Court and the Court of Appeals recognizes the substantive evidentiary import of

medical records (as reflected MRE 803(6)) and their inherent trustworthiness. As this Court explained in People v Kirtdoll, 391 Mich 370; 217 NW2d 37 (1974):

"[T]he records are made and relied upon in affairs of life and death. Moreover, amidst the day-to-day details of scores of hospital cases, the physicians and nurses can ordinarily recall from actual memory few or none of the specific data entered; they themselves rely upon the record of their own action. . . ."

Likewise, as the court explained in <u>Globe Indemnity Co</u> v <u>Reinhart</u>, 152 Md 439, 446-447; 137 A 43, 46 (1927) (which this Court in <u>Kirtdoll</u> cited with approval):

[A hospital record] is a record required by the hospital authorities to be made by one whose duty it is to correctly make the entries therein contained. So far as the hospital is concerned, there could be no more important record than the chart which indicates the diagnosis, the condition, and treatment of the patients.

The reliability of medical records to describe accurately what took place does not depend on the independent recollection of those who authored them. A medical record is inherently trustworthy and is therefore just as conclusive concerning the events that transpired as would be the testimony of the nurses and doctors who made that record. On this basis alone, it is clear that the Court of Appeals below erred in affirming a verdict based on expert testimony that not only lacked the required substantial support in the factual record of what took place (here, the medical records), but actually contradicted that established record.

2. The Established Medical Record in this Case Provides the Only Reliable Account of What Occurred During Ms. Craig's Labor and Plaintiff's Birth

Determining whether an expert's causation theory is substantially supported by the medical record is the judicial gatekeeper's first step in evaluating the reliability and admissibility of such expert testimony. Neither the trial court nor the Court of Appeals engaged in the required gatekeeping analysis of whether Plaintiff's experts' causation theory was substantially supported by the established factual evidence as reflected in the medical record of what took place. Indeed, the Court of Appeals even found the plain inconsistencies between the medical

record and the Plaintiff's experts' causation testimony to be the appropriate exercise of expert "interpretation" of record facts, rather than a proper basis for excluding the expert testimony as unsupported by and inconsistent with the established facts.

a) Administration of Pitocin

The Oakwood medical records establish the following facts with regard to the administration of Pitocin to Ms. Craig:

- (1) Dr. Gennaoui wrote an order for 10 units (1 amp) of Pitocin. (Doctor's Orders [87a]);
- Under Oakwood protocol, a nurse filling a doctor's order for Pitocin would have taken a new 1000cc bottle (or bag) of solution, added 1 amp of Pitocin to it, and labeled that bag accordingly. The bag containing the Pitocin would then have been run through an IVAC, which is a monitor/regulator that allows the administration of precise dosages. The IVAC would, in turn, be connected to the IV line that was already connected to the patient and through which a hydrating fluid (such as the solution originally given to Ms. Craig) was being administered. Pitocin would never be added directly to the existing IV bag; 12
- (3) The initial dosage of Pitocin administered to Ms. Craig was 2 milliunits (mu), and was increased in 2 mu increments progressively throughout the day until the dosage reached 18 mu. ¹³ The dosage remained at 18 mu until it was discontinued at 6:00 p.m. ¹⁴

⁹ Dr. Mitchell Dombrowski: 335a, 337a; Nurse Rhea Hill: 348a.

¹⁰ Dr. Gatewood: 188a, 213a; Dr. Dombrowski: 336a, 338a; Nurse Hill: 348a.

¹¹ Dr. Gennaoui: 278a-281a, 283a; Nurse Hill: 348a.

¹² Dr. Gennaoui: 278a-281a; Nurse Hill: 350a, 359a-361a.

Nurse's Notes [83a]; Labor Record [84a]; Summary of Dr. Gennaoui [88a]; IV Induction Record [89a]; Dr. Mitchell Dombrowski: 344a-345a.

Nurse's Notes [83a]; Labor Record [84a]; Summary of Dr. Gennaoui [88a]; Dr. Gennaoui: 269a-270a, 286a-289a; Nurse Jill Paslaiko: 397a.

Significantly, Dr. Gatewood, Plaintiff's only expert to render an opinion as to the amount of Pitocin administered, acknowledged that the Pitocin dosages reflected in the medical record were within normal limits, and that the incremental increases administered during the course of labor were also proper. (222a).

b) Strength and Duration of Contractions

The Oakwood medical records reflect the contemporaneous clinical observations of the nurses and doctors who were present during labor and delivery and Plaintiff's experts should not have been permitted to re-interpret or re-write the facts reflected in the medical record. Those records establish the following:

- (1) From 11:30 a.m. to the time that Pitocin was discontinued at 6:00 p.m., Ms. Craig's contractions were monitored at least thirteen times by way of "palpation" of her abdomen, which involves using one's hand to feel the strength of the contractions;
- (2) During that time, Ms. Craig's contractions were never recorded as being more than moderate;
- (3) Ms. Craig's contractions were always two to four minutes apart. They were three to four minutes apart until 4:00 p.m., at which time they began to occur every two to three minutes.

[Nurse's Notes [83a]; Labor Record [84a]; Dr. Gennaoui Summary [88a]; IV Induction Record [89a]; Dr. Gatewood: 458a-501a; Dr. Bernal: 299a-303a; 310a; 372a; Nurse Paslaiko: 377a-399a].

c) Plaintiff's Condition at Birth

According to the Oakwood medical records, Plaintiff was, at birth, healthy neurologically and in all other respects. These records reflecting Antonio Craig's condition at birth and his course in the neonatal nursery, together with the testimony of the doctors and nurses who examined him at birth and during the days thereafter establish the following facts:

- (1) Plaintiff's APGAR scores which measure such neurological functions such heart rate, respiration, tone, reflexes, and skin color at 1 and 5 minutes after birth were 9 and 10 (respectively) out of 10;¹⁵
- (2) Plaintiff's feeding and urine output were normal;¹⁶
- (3) Plaintiff's mental status was alert and active, and his pupils were equally reactive, round, and reacting to light; 17
- (4) Plaintiff exhibited normal neonatal reflexes; 18
- (5) There was no indication of abnormal pressure within Plaintiff's skull;¹⁹
- (6) Plaintiff was found to be a "well term male newborn."²⁰

d) MRI Report

Dr. Gabriel interpreted the MRI of Plaintiff's brain taken in 1993, 13 years after Plaintiff's birth, as revealing abnormalities in the cortex and "asymmetry" of the brain itself, but the established medical evidence as reflected in two MRI reports from two neuroradiologists (one from Children's Hospital and one from the University of Michigan Hospital) do not support Dr. Gabriel's "re-interpretation" of the MRI.

Neither MRI report offered a diagnosis of Plaintiff's condition or even an impression as to what caused the brain abnormality or when it was sustained. As Antonio Craig's pediatric neurologist, Dr. Michael Nigro, explained, these reports do not describe any abnormality of the

Nurse Rhea Hill: 354a-355a; Nurse Jill Paslaiko: 396a. The APGAR score was erroneously recorded as 8-9 in the Admission and Progress Notes (85a) and in Dr. Gennaoui's summary (88a). There is no substantial difference between the scores. (See 427a).

¹⁶ Dr. Ronald Gabriel: 250a.

Admission and Progress Notes [85a]; 333a-334a; 439a.

¹⁸ Admission and Progress Notes [85a]; 439a-440a.

¹⁹ Admission and Progress Notes [85a]; 439a-440a.

²⁰ Admission and Progress Notes [85a]; 334a; 440a.

cortex, nor any "asymmetry" of the brain that might indicate birth-related trauma. (416a-420a). Dr. Gabriel had no factual foundation for his complete disregard of these very same MRI reports, which are part of the established medical record. Moreover, Dr. Gabriel, a pediatric neurologist, does not have expertise in neuroradiology and his re-interpretation of an MRI film cannot supplant a neuroradiologist's MRI interpretation and report.

3. Whether Examined Separately or Together, Plaintiff's Experts' Causation Testimony is Legally Deficient Because it Fails to Describe a Logical Sequence of Cause and Effect That is Substantially Supported by the Established Factual Record

Established Michigan authorities require that an expert's causation testimony describe a logical sequence of cause and effect and that it be substantially supported in the factual record. Mulholland, supra; Skinner, 445 Mich at 164-165; Kaminski, 347 Mich at 422. In addition to the lack of factual support for Plaintiff's experts' testimony, each expert's opinion is also missing an essential causal sequence. Neither of the expert's opinions as to causation can stand alone and each expert's deference to and dependence upon the other's opinion and expertise did not supply the missing piece essential to describe a complete, logical sequence of how Antonio Craig's alleged brain injury occurred.²¹

Oakwood and the defense witnesses generally have never disputed that an overdose of Pitocin *could cause* injuries to a fetus, but both the trial court and the Court of Appeals (see slip op at 5) failed to appreciate that an acknowledgement of Pitocin's **potential** for causing fetal injuries if administered improperly is not a substitute for evidence in this case *establishing* that an overdose of Pitocin was administered. Moreover, an acknowledgment that an overdose of

This argument was presented in both a directed verdict motion (441a-447a), and in a motion for JNOV.

Pitocin or misuse of Pitocin *could* theoretically cause harm to a baby <u>in utero</u> under some circumstances does not provide support for the proposition that the traumatic "pounding and grinding" of the fetal head could ever even occur *under any circumstances*.

Significantly, Plaintiff's obstetrical expert, Dr. Gatewood, conceded he could not even speculate as to how the overdose of Pitocin and resulting severe uterine contractions that he assumed took place could have injured Plaintiff's brain:

Now as I stated yesterday, I'm not about to get up here and tell you that because of the hypoxia this is what happened to the baby's brain. That's the purview of a neurologist.

Q. The mechanism by which hypoxia damages the fetal brain is acidosis, is it not?

A. You'd have to ask [a] neonatologist or a neurologist.

(See 193a, 209a-210a, 231a). Rejecting the possibility that trauma in utero could account for Antonio's condition (231a), Dr. Gatewood assumed there must have been an hypoxic episode during the labor – a cessation of blood flow through the umbilical cord that somehow injured only Antonio's brain and no other organs. Yet, Dr. Gatewood deferred to Plaintiff's pediatric neurology expert, Dr. Gabriel, as to just how the hypoxic episode he assumed had occurred injured Plaintiff's brain. Translating Dr. Gatewood's deference to Dr. Gabriel into logic, it is clear that Dr. Gatewood's causation scenario is missing an essential sequence – what caused the brain injury in utero? This essential sequence Dr. Gatewood left for Dr. Gabriel to supply.

Whether as a consequence of a lack of preparation or a strategic failure to coordinate his testimony with that of Dr. Gatewood, Dr. Gabriel was not only unable to supply the missing causal sequence, but he expressly rejected Dr. Gatewood's causal scenario that an hypoxic-ischemic episode must have occurred that then led to the brain injury. (245a-246a). In his attempt to provide the missing causal sequence by which the brain injury might have occurred during labor, Dr. Gabriel theorized that Plaintiff sustained head trauma from the "pounding and

grinding" of the head against some hard structure in the pelvic anatomy that he could not specify. If it was a strategic objective to have Dr. Gabriel fill in the missing and essential causation sequence – how did the hypoxic episode Dr. Gatewood theorized actually cause a discrete injury to the child's brain? – that strategy plainly backfired.

There appears to be little doubt that Dr. Gabriel rejected Dr. Gatewood's assumption that an hypoxic episode occurred in an attempt to avoid the crushing weight of recognized medical science (and common sense) establishing that a baby who suffers a loss of adequate blood flow during labor will emerge at birth in a compromised condition, manifesting severe systemic impairments, including multi-organ dysfunction and neurological deficits. (See 245a-246a, 249a). Yet, the medical records and testimony of fact witnesses established that Antonio Craig was born without any such symptoms or manifestations of impairment, and thus Dr. Gabriel's only strategic ploy for avoiding the challenge that medical science poses to his opinion was to fashion a theory of fetal brain injury unknown to medical science. In proposing the "pounding/grinding" theory of fetal brain injury, Dr. Gabriel therefore had no fear of impeachment by medical or scientific literature directly addressing such a mechanism of injury since such a phenomenon has never been recorded in any field of medical science.

By rejecting Dr. Gatewood's scenario that a hypoxic episode somehow led to the brain injury, Dr. Gabriel temporarily avoided a clash with the abundant medical literature confirming the symptoms of fetal hypoxia that would be manifest at birth. But Dr. Gabriel's efforts to construct an alternative mechanism of causation that could even describe a logical sequence of cause and effect extending from the point of the alleged negligence all the way to the point of the alleged brain injury failed by his own admissions. Dr. Gabriel's opinion that Plaintiff was injured by the "pounding and grinding" of his head against a part of the pelvic anatomy which

Dr. Gabriel could not identify exposed his lack of the expertise and knowledge necessary even to offer a coherent theory as to how the head and brain were traumatically injured.

When pressed to identify what structures in the pelvic anatomy could have caused the traumatic head injury, Dr. Gabriel acknowledged that **he was incompetent to do so**:

A. I don't want to characterize the mother's anatomy. That's not my area of knowledge.

* * *

A. No. I'm not an obstetrician and I don't want to get into obstetrical anatomy, physiology or management.

* * *

A. Once again, and I'm going to repeat myself, I will not get into maternal anatomy. I'm a child neurologist.

* * *

- Q. The cervix expands, isn't that correct?
- A. The same answer. You're asking obstetrical questions which I'm not competent to answer.

* * *

- Q. Doctor, can you explain to the jury, how the head was either being crushed against the pelvis, pounded against the pelvis, grounded against the pelvis during uterine contractions but at the same token how or why it would be able to rotate through pelvis for normal delivery?
- A. That's an obstetrical question and I don't think I'm competent to answer that in terms of the anatomy.

* * *

- Q. Now, can you tell, Doctor, where this pelvic rim is that you've been telling us about?
- A. You're asking again a question which is obstetrical in nature. I will not get into that. [See 242a-244a, 251a-252a, 255a-258a (emphasis added)].

Dr. Gabriel's theory assumes there are hard structures in the pelvic anatomy against which a fetal head can "pound and grind," but he could not even name such a structure and he acknowledged he was incompetent to do so. Moreover, no obstetrical expert, not even Plaintiff's own expert, Dr. Gatewood, offered support for the notion that there are any

hard structures in the pelvic anatomy against which the fetus' head could be "pounded" and traumatized. Dr. Gabriel conceded, as did Dr. Gatewood, that there was no cephalopelvic disproportion in this case (i.e., a fetal head too large to pass easily through the birth canal) that could possibly have obstructed or interfered with the normal descent and emergence of the baby's head during labor and delivery. (227a, 233a).

Thus, like Dr. Gatewood's causal scenario, Dr. Gabriel's scenario fails to describe a complete, logical sequence of cause and effect that includes the most proximate, the most essential sequence – exactly how a traumatic impact to the fetal head could possibly have occurred in utero. Put in logical terms, if Dr. Gabriel admits that – (1) he is "incompetent" to discuss any matters involving "obstetrical anatomy, physiology or management"; (2) that he does not know even generally the anatomy of the pelvic area; and (3) that he does not know what part of the pelvic anatomy against which the fetal head was "pounded" – then he cannot describe, much less offer substantial factual record support for, the critical causal sequence at issue – how did the head trauma that theoretically injured the brain take place?

Thus, in addition to the utter lack of support in the factual record for Plaintiff's experts' causation testimony, it is apparent that their theories, whether examined separately, or as two pieces of a puzzle, fail even to describe a logical sequence of cause and effect extending from Defendants' alleged negligence to the alleged injury to Antonio Craig's brain during labor. On this basis alone, judgment NOV is required.

4. Plaintiffs' Experts' Theory That an Overdose of Pitocin Was Administered During Labor is Contrary to the Established Factual Record

Leaving aside any other differences in their testimony, both of Plaintiff's experts ultimately premised their incomplete, and thus inadequate, theories as to the cause of Plaintiff's neurological defects on the factual assumption that Ms. Craig received a massive overdose of

Pitocin. There is, however, no evidence in the factual record that would permit a reasonable inference that any such thing occurred. The legitimate factual evidence of what took place during labor, as described in the medical records and by those nurses and doctors who cared for Ms. Craig and her son, establishes that: (1) Ms. Craig received the ordinary, proper dose of Pitocin which caused "mild" to "moderate" contractions; and (2) her son was born in good health and with no symptoms of neurological compromise or any other impairment.²²

Yet, in disregard of the testimony of the medical witnesses and the detailed, reliable medical records confirming the proper administration of Pitocin and the moderate uterine response to the Pitocin, Dr. Gatewood offered the following scenario at trial (which Dr. Gabriel accepted as fact in support of his "pounding and grinding" theory): despite the IV induction record showing the appropriate administration of Pitocin, Dr. Gatewood "interpreted" (see 154a) or, more realistically, rewrote, the medical record to indicate that two separate IV bags containing Pitocin were mistakenly administered to Ms. Craig without any one of the doctors and nurses attending Ms. Craig noticing such a flagrant error and its inevitable clinical manifestations. Dr. Gatewood admitted that this was not his "interpretation" of the medical records at the time of his deposition, and that he came up with his overdose theory after reviewing the records again with Plaintiff's counsel. (115a-156a).

According to this fantastic theory, Oakwood Nurse Karen Quinlan supposedly gave Pitocin to Ms. Craig by injecting it directly into an IV bag, and then another nurse, Joyce Tyra (inexplicably), also mixed a **second** bag of Pitocin and administered it in complete disregard of the medical record chart plainly indicating that Pitocin had already been administered. (See

Defendants objected to the lack of any evidentiary support for Plaintiff's Pitocin overdose theory during the testimony of Plaintiff's expert obstetrician, Dr. Gatewood (see see 169a, 179a-187a), but the trial court's only response was "you can ask on cross-examination." (180a). Defendants presented the issue again to the trial court in their motion for JNOV.

163a-172a, 214a-217a). These two nurses who attended Ms. Craig regularly reviewed the medical chart and both followed the one doctor's order addressing the following three tasks: (1) the setting up of the original IV; (2) the setting up of an external monitor; and (3) the administration of Pitocin (see Doctor's Orders [87a]; Dr. Gennaoui: 261a-265a). Both of their signatures appear on the order. According to Dr. Gatewood, these two nurses somehow became confused as to who was supposed to be administering the Pitocin to Ms. Craig, and this confusion led **both** nurses to give the dose of Pitocin the doctor ordered.

No explanation was ever given for how this supposed mix-up could even plausibly, let alone probably, have occurred; the scenario depends on the facially nonsensical proposition that Nurse Tyra looked at the order for the administration of Pitocin, saw that Nurse Quinlan had already administered the Pitocin, and nevertheless proceeded to give Ms. Craig a second dose. As Ms. Craig's treating physician, Dr. Gennaoui, testified, the only conceivable "mistake" committed was the incorrect description by Nurse Tyra of the IV bag containing the Pitocin in the IV induction record [89a], one of the many records of Ms. Craig's labor:

- Q. Doctor, how do you explain the switcheroo.
- A. There is no switcheroo. You can see the entry of the nurse's on the nurse's record. At 10:00 o'clock this is the IV that was started. . . . then later on, another IV was started with the medicine in it. The way it's written here, you can see the type of solution and there is an error in the in in where it was placed.
- Q. Okay. Who made the error, just so we're clear here?
- A. Nurse J. Tyra.
- O. Nurse Tyra made the error?
- A. Yes.
- Q. What did she do, allegedly what did she do wrong?

A. Well, she wrote – she wrote what's the IV solution for the IV piggyback [the second solution in which the Pitocin was mixed] in the place of the primary IV solution, it was just a -- twist. [284a-285a]

In complete disregard of the facts of the labor as described in detail in the record, Dr. Gatewood was permitted to re-invent the factual sequence of what occurred and opine to a jury that two containers of Pitocin were mistakenly administered to Ms. Craig. According to Dr. Gatewood, this massive overdose took place while the doctors and nurses were attending Ms. Craig, contemporaneously recording her contractions as "mild to moderate," and noting her normal, uncomplicated responses to the Pitocin. [See Nurses Notes [83a]; Labor Record [84a]; Summary of Dr. Gennaoui [88a]; IV Induction Record [89a]; Dr. Gatewood: 458a-501a; Dr. Bernal: 299a-303a; 310a; Nurse Geraldine Schmidt: 372a; Nurse Jill Paslaiko: 377a-399a]. Defense witnesses, who, unlike Dr. Gatewood, were knowledgeable about Oakwood's nursing practices with regard to the administration of Pitocin and who carefully read the detailed medical record, testified that there was nothing in the record even suggesting that two IV bags containing Pitocin were administered. (Oakwood Nurse Rhea Hill: 348a-350a).

Dr. Gatewood's opinion that an overdose of Pitocin was given also necessarily requires the assumption, again in disregard of the medical records and fact witnesses' testimony, that several Oakwood protocols and customary procedures for the administration of Pitocin were inexplicably and persistently violated. First, under Dr. Gatewood's theory, Nurse Quinlan would have had to have injected the Pitocin directly into the original IV bag. However, the evidence was undisputed that it would have been a violation of established, routine Oakwood nursing protocols to do so because those protocols require the use of a full IV bag for the administration of Pitocin and the use of an IVAC, a machine that monitors the administration of the Pitocin. There is no basis in the Oakwood nursing protocols nor in the medical records for Dr.

Gatewood's assertion that Pitocin must have been added directly to the IV bag already in place. (See Nurse Hill: 348a-350a).²³

Dr. Gatewood's overdose theory also depends upon the assumption that a second established nursing protocol was violated – a protocol requiring the placement of a conspicuous label on the IV bag containing the Pitocin. According to Dr. Gatewood, Nurse Quinlan must have violated this protocol and failed to place the identifying label on the IV bag containing Pitocin. Otherwise, Nurse Tyra could not possibly have assumed that the original IV bag contained only hydrating solution and then proceeded to administer a second dose of Pitocin through a second bag. Even Dr. Gatewood acknowledged that it seemed "absurd" that Nurse Tyra would have done this. (219a-220a). Both Nurse Tyra (309a, 347a) and Nurse Quinlan (374a-376a) were experienced, conscientious obstetrical nurses. Dr. Gatewood could not and never even attempted to explain why two such professionals would suddenly lapse into a pattern of deviation from hospital protocol.

On the face of this record, the **only** reasonable inference is that Nurse Tyra, and not Nurse Quinlan, administered the Pitocin through an IVAC machine (as reflected in the 11:35 a.m. entry made by Nurse Tyra in the Nurse's Notes [83a] as well as by her signature on the IV induction record [89a]; see also 261a-265a) and then made the <u>single</u> (and harmless) mistake of transposing the original (lactated ringers) and Pitocin-containing (dextrose and water) IV solutions on the IV induction record.²⁴ **However, whether Nurse Tyra committed a clerical**

²³ Significantly, while Dr. Gatewood testified that it would be acceptable at his hospital to inject Pitocin directly into an existing IV (218a), he admitted that he had never worked at Oakwood and that he had no knowledge of Oakwood's nursing procedures for the administration of Pitocin. (211a-212a).

There is no dispute that Nurse Tyra used a slightly different IV solution (D5W) than that originally specified by Dr. Gennaoui (lactated ringers) when she mixed the Pitocin and administered it to Ms. Craig through the IVAC. However, as Dr. Gennaoui made clear, the Footnote continued on next page ...

was probably administered. When the established factual record does not permit such an inference, neither an expert nor a layperson may rationally accept it as fact. The Plaintiff's experts' opinion that an overdose of Pitocin was given – this permissible expert "interpretation" of the medical record, from the Court of Appeals' perspective – is supposition only and does not, as the Court of Appeals mistakenly concluded, present a "credibility issue" for jury consideration.

Dr. Gatewood's fantastic cascade of medical errors cannot be characterized as "probable." Nothing in Nurse Tyra's clerical error and nothing in the remainder of the established medical evidence provide factual support for the necessary inference that, more likely than not, Ms. Craig was given an overdose of Pitocin. As this Court explained in <u>Kaminski</u>, an explanation for what occurred – no matter how imaginative – remains inadmissible supposition if the evidence is without "selective application" to that explanation:

As a theory of causation, a conjecture is simply an explanation consistent with known facts or conditions, but not deducible from them as a reasonable inference. There may be two or more plausible explanations as to how an event happened or what produced it; yet, if the evidence is without selective application to any one of them, they remain conjectures only. On the other hand, if there is evidence which points to any one theory of causation, indicating a logical sequence of cause and effect, then there is a juridical basis for such a determination, notwithstanding the existence of other plausible theories with or without support in the evidence.

Kaminski, 347 Mich at 422 (quoting <u>City of Bessemer v Clowdus</u>, 261 Ala 338, 394; 74 So 2d 259 (1954) (Emphasis added). And, in the words of this Court in <u>Skinner</u>, 445 Mich at 164-165:

We want to make clear what it means to provide circumstantial evidence that permits a reasonable inference of causation. As <u>Kaminski</u> explains, at a minimum, a causation theory must have some basis in established fact. However,

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record would not necessarily show if Nurse Tyra had asked his permission to use a different solution and, in any event, it makes no difference which solution is used (272a, 277a-278a). Dr. Gatewood acknowledged this point as well. (229a).

a basis in only slight evidence is not enough. Nor is it sufficient to submit a causation theory that, while factually supported, is, at best, just as possible as another theory. Rather, the plaintiff must present substantial evidence from which a jury may conclude that more likely than not, but for the defendant's conduct, the plaintiff's injuries would not have occurred."

At trial, Defendants explained the confusing notation at issue as Nurse Tyra's clerical error when she entered the IV solutions on the induction record. While this explanation surely makes the most sense, given the medical record as a whole and the testimony of the doctors and nurses, its acceptance by the trial court, or the appellate courts is not required in order to determine that this record does not support the inference that, more likely than not, an overdose of Pitocin was given. As Kaminski and Skinner make clear, if the evidentiary record does not affirmatively support as probable the factual inferences upon which the expert's theory depends, that theory has no business in a courtroom. Skinner, 445 Mich at 164-165. Here, the inference that an overdose of Pitocin was given not only lacks any support in the established record of what occurred during labor, the established factual record actually opposes such an inference. Because Plaintiff's experts' assumption that an overdose of Pitocin was given is essential to the foundation of both experts' theories, the lack of support in the evidence for the proposition that an overdose was probably administered collapses both theories. A judgment NOV on this basis, as well, is therefore required.

5. Defendants are Entitled to JNOV Because The Factual Record Contradicts the Theory of

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Plaintiff's counsel also attempted during closing argument to suggest to the jury an alternative theory for how an overdose of Pitocin was supposedly given, namely, that a double-dose of Pitocin was placed into the same IV bag. (456a-457a). The "support" offered for that contention was that when Ms. Craig was admitted to the recovery room following the delivery, there were two amps of Pitocin in her IV bag – twice the amount ordered by Dr. Gennaoui. (See Recovery Room Record, 90a). However, even the testimony of Plaintiff's own expert obstetrician, Dr. Gatewood, makes clear that the "two amp" reference in the recovery room records simply means that two amps of Pitocin were administered after the delivery in order to expel the placenta and reduce bleeding. (See 221a; 232a).

Plaintiff's Experts That Ms. Craig Experienced Severe and Prolonged Contractions

Both Plaintiff's experts based their testimony on material factual assumptions that find no support in the factual record and actually oppose the facts reflected in the record. Both experts assumed that Ms. Craig experienced extremely severe and prolonged uterine contractions as a result of the supposed Pitocin overdose. Indeed, the assumption that severe uterine contractions took place does not even find refuge in the testimony of Plaintiff's experts, who, as a result of poor preparation or the sheer difficulty of keeping their theories afloat in the absence of record support, acknowledged they were not able to determine the severity of the contractions from the external monitor (Dr. Gabriel admitted that he did not even know how the monitor worked), and that the severity of contractions had to be determined by the attending doctors and nurses through palpation of the abdomen. (224a-225a; 259a-260a; 502a).²⁶

It was undisputed that if an overdose of Pitocin was mistakenly given, as Dr. Gatewood supposed, and as Dr. Gabriel automatically accepted as fact from Dr. Gatewood, this would have brought on contractions causing "extremely intense pain" (Dr. Gatewood: 208a; Dr. Seymour Zeigleman: 400a), such that Ms. Craig would have been "screaming her lungs out." (Dr. Gennaoui: 296a). However, the Oakwood Hospital medical records – created by the nurses and doctors who attended Ms. Craig – fail to provide the requisite support for the proposition that, more likely than not, Ms. Craig experienced such severe uterine contractions. As with the supposition that a Pitocin overdose was given, the established medical record actually opposes the necessary assumption that the contractions were severe. The contractions was measured regularly throughout labor by direct palpation of the abdomen, a method that Dr. Gatewood admitted was necessary in order to determine the severity of the contractions. (See 224a-225a).

²⁶ This argument was advanced in Oakwood's motion for JNOV.

As set forth previously, <u>infra</u> at pp 6, 20, at no point do the medical records reflect that the contractions were more than "moderate" in strength or more frequent than every two minutes.²⁷ Nor do the records describe any unusual patient response to the Pitocin.

Not only does the established factual record provide no support for the inference that the contractions were severe, but Dr. Gatewood himself – the creator of the Pitocin overdose and violent uterine contraction scenario – admitted that an external monitor alone cannot determine the strength of uterine contractions. (224a-225a, 502a). And, Dr. Gabriel admitted he did not even know how an external monitor works (259a-260a). Thus, the only legitimate factual evidence in the record as to the strength of the uterine contractions was the medical record and testimony of the doctors and nurses in attendance, all of which established that the contractions were never more than "moderate" throughout the labor.

It would not have required a protracted analysis of the record in order for the trial court and the Court of Appeals to have discovered that, based on Plaintiff's experts' own admissions, there was no evidence of severe uterine contractions. Add to that the lack of any support in the established medical record for such an inference and Plaintiff's experts' assumption that Ms. Craig experienced severe uterine contractions is not just speculation, it is folly. Judgment NOV for Defendants on this basis, as well, is required.

6. The Claim by Plaintiff's Experts That Oakwood Committed Professional Negligence by Not Having an Internal Uterine Pressure Catheter Also Lacks Support in the Established Facts

In addition to his fanciful Pitocin overdose theory, Dr. Gatewood theorized that Oakwood committed professional negligence by not having available an internal uterine pressure catheter

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²⁷ Contractions are categorized as "mild" (the contracted abdomen is as firm as the end of one's nose), "moderate" (the contracted abdomen is as hard as one's chin), and "strong" (the contracted abdomen is as hard as one's forehead). (342a-346a, 368a).

(IUPC) for the purpose of monitoring the strength of uterine contractions. (160a-161a). Like Dr. Gatewood's other theory as to the Pitocin overdose, this theory as to the necessity and utility of an IUPC does not "fit" the established facts of the case because Ms. Craig's treating obstetrician, Dr. Gennaoui, testified that he would not have used an IUPC even if it had been available because Ms. Craig's clinical presentation did not justify its use.²⁸

A plaintiff in a medical malpractice case must offer expert testimony, well-founded in the factual record, to support both the element of a breach of the standard of care and the element of causation in fact. Locke v Pachtman, 446 Mich 216, 223-224; 521 NW2d 586 (1994). As a logical proposition, Oakwood's failure to have an IUPC could not have been a cause-in-fact of anything related to Plaintiff's labor and delivery unless Plaintiff could establish that Dr. Gennaoui would have used it if it had been available.

Plaintiff presented no evidence challenging the testimony of Dr. Gennaoui that there was no indication for using an IUPC on Ms. Craig, and that he would not have used one even if it had been available. (298a).²⁹ In rejecting Oakwood's argument on this issue, the Court of Appeals missed the point by holding that "Dr.Gennaoui's testimony does not negate Oakwood's obligation to follow the standard of practice by having internal uterine monitors available. Rather, it creates a question of fact for the jury." Slip op at 8. Because Dr. Gennaoui, the treating obstetrician, testified, without challenge, that he would not have used an IUPC even if Oakwood had provided one, Plaintiffs have failed to provide the necessary evidence to support the element of causation

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²⁸ This argument was raised both in Oakwood's directed verdict motion (441a), as well as its motion for JNOV.

²⁹ Dr. Seymour Zeigelman, another obstetrical expert, went even further, pointing out that because of the risk of infection, the use of an IUPC was <u>contraindicated</u> when the membranes have spontaneously ruptured. (401a-403a).

in his case against Oakwood. Oakwood moved for and was entitled to either a directed verdict or judgment NOV as to this claim as well.³⁰

C. The Court of Appeals Erred in Failing to Recognize and Enforce the Trial Court's Mandatory Gatekeeping Responsibility to Ensure That Only Reliable Expert Testimony is Presented to a Jury

MRE 702 and the Michigan authorities that have interpreted and applied this rule impose a mandatory obligation on the trial courts to evaluate whether expert testimony is objectively validated outside the courtroom and substantially supported by the factual record in the courtroom. As both the trial court and the Court of Appeals in the present case failed to appreciate, this fundamental gatekeeping obligation is not discretionary and cannot be avoided by characterizing a challenge to expert testimony as a matter of "weight" or "credibility" for the jury to determine.

Had the trial court followed the legal mandate to evaluate the reliability of Plaintiff's experts' testimony, it would have discovered the lack of any foundation in medical science or in the record facts supporting Plaintiff's causation theory. Had this gatekeeping responsibility been discharged, the cascade of erroneous rulings that unfairly and repeatedly prejudiced Oakwood during this five-week trial would have been prevented. Instead, Plaintiff's experts, who had neither personal knowledge of the facts nor respect for the factual record were permitted to tell the jury a story about what took place during the labor and delivery – a story that was nothing more than speculation in defiance of medical science and the established evidentiary record.

Plaintiff's obstetrical expert, Dr. Gatewood, presented as evidence the fantastic Pitocin overdose scenario; Dr. Gabriel, Plaintiff's pediatric neurology expert, told the jury that Antonio

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Even if only this one basis for judgment NOV were granted, the law would require a new trial as to all claims because there can be no confidence that the jury's verdict was not based on this legally insufficient claim. See Solomon v Shuell, 435 Mich 104; 457 NW2d 669 (1990).

Craig suffered brain injury from the traumatic "pounding" and "grinding" of his head into some unidentified part of the pelvic anatomy – a mechanism of fetal brain injury never even recognized as anatomically possible in any branch of medical science. (234a-237a, 242a-244a).

While the Court of Appeals vaguely described Dr. Gabriel's theory as involving reduced blood flow to the brain with a "traumatic component," Dr. Gabriel confirmed during his direct examination that head trauma was the lynchpin of his causation theory:

I think the injury occurred in two ways. First there was a compression of the head through grinding experience with the head in the pelvic rim, accentuated by the high uterine pressures from Pitocin producing decelerations which were quite marked after a certain point in time.

And this resulted in compression, producing a compression injury over the surface of the brain. And this in turn also resulted in elevation in ven[o]us pressures of the brain which then impedes arterial blood flow. [234a-235a.]

Dr. Gabriel further emphasized the point on cross-examination:

- Q. Well, in all likelihood, Doctor, if there is severe enough trauma to cause bleeding, wouldn't that raise intracranial pressure?
- A. No, not necessarily.
- Q. So in all likelihood then you're saying that the head was pounded into the pelvis and grounded into the pelvis, that that wouldn't cause enough bleeding to cause any swelling of the brain either?
- A. Your exaggerating for effect. What happens is that two things. Number one, you have the compression injury, and number two, this raises the ven[o]us pressure which then in turn reduces the blood flow, so you have two different things going on. Reduce blood flow to the watershed or distal most portions of the brain, and you have this compression over the surface. So you have two different things going on. And I don't think you can separate out the two.
- Q. So in your theory there was traumatic damage to the brain and you think there was bleeding in the brain but there was no increase of pressure?
- A. Correct. [247a-248a (emphasis added).]

As Dr. Gabriel made clear during the discovery phase of this case, he could offer no objective, independent validation from medical science for his theorized mechanism of fetal

brain injury. (Deposition of Dr. Ronald Gabriel [111a-112a, 127a-128a]). Not one peer-reviewed article, textbook excerpt, or even anecdotal report ever emerged before or during this five-week trial to establish that the "pounding and grinding" phenomenon theorized by Dr. Gabriel was even anatomically possible, much less that it was recognized by medical science as a known mechanism of fetal brain injury during labor.

Despite the presentation of Dr. Gabriel's own pretrial testimony confirming the lack of any independent validation in medical science for his "pounding and grinding" theory of fetal brain injury, the trial court rejected Defendants' request for an Davis-Frye/MRE 702 hearing on the ground that Defendants had not proven that this theory was unreliable. In upholding this erroneous ruling, the Court of Appeals concluded that because Defendants had not proven the "pounding and grinding" theory to be "novel" scientific evidence, such a theory was admissible evidence suitable for presentation to a jury. Like the trial court, the Court of Appeals panel determined that no examination of the reliability of Dr. Gabriel's causation theory was necessary in the absence of Defendants' "proof" of its novelty in the realm of medical science.

1. Michigan Law Obligates the Trial Courts to Conduct an Examination of the Reliability of Proposed Expert Opinion Testimony When a Challenge to the Testimony is Made

In approving the trial court's refusal to conduct any examination to ensure that Plaintiff's experts' "pounding and grinding" theory was recognized and validated in the experts' specialized fields and supported by record facts, the Court of Appeals' published opinion deviates from and challenges the long line of controlling <u>Davis-Frye/MRE</u> 702 case authorities³¹ and MRE 702

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See, e.g., Mulholland, 432 Mich 395; Young, 418 Mich 1; People v Tobey, 401 Mich 141; 257 NW2d 537 (1977); People v Barbara, 400 Mich 352; 255 NW2d 171 (1977); Spect Imaging, Inc v Allstate Ins Co, 246 Mich App 568; 633 NW2d 461 (2001); Tobin v Providence Hospital, 244 Mich App 626; 624 NW2d 548 (2001); Stitt v Holland Abundant Life Fellowship, 243 Mich App 461; 624 NW2d 427 (2000); Anton v State Farm Mut Auto Footnote continued on next page ...

itself. These case authorities and MRE 702 comprise the rule of law that should have guided the trial court's and the Court of Appeals' analysis of Defendants' challenge to the reliability of Plaintiff's experts' testimony.

Contrary to MRE 702 and the governing case authorities, the Court of Appeals panel adopted a rule of law that opens the door to any expert testimony that has not been proven to be "scientifically novel." Further, the Court of Appeals' opinion relieves the trial courts of any responsibility to even examine the reliability of proposed expert testimony whenever the party challenging the testimony fails to prove that the theory is "novel." Slip op at 4.

Putting aside the vexing question of what "novel" could possibly mean if it does not include a theory of fetal brain injury that has never even been recognized as anatomically possible by anyone other than Dr. Gabriel, the Court of Appeals' disregard of MRE 702 and the controlling case authorities requiring trial courts to do what Defendants asked the trial court to do is plainly wrong. The Court of Appeals clearly misapplied MRE 702 in concluding that a Davis-Frye/MRE 702 examination of the reliability of Dr. Gabriel's testimony depended on a showing by Defendants that the theory is "novel." The trial court was required to conduct an examination of the reliability of (not merely the novelty of) Dr. Gabriel's testimony. Before Dr. Gabriel's causation theory could be properly presented to a jury as evidence, the law required the

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Ins Co, 238 Mich App 673; 607 NW2d 123 (1999); Nelson v American Sterilizer Co (On Remand), 223 Mich App 485; 566 NW2d 671 (1997); People v Lee, 212 Mich App 228; 537 NW2d 233 (1995); People v Adams, 195 Mich App 267; 489 NW2d 192 (1992); People v Gistover, 189 Mich App 44; 472 NW2d 27 (1991); People v King, 158 Mich App 672; 405 NW2d 116 (1987); People v Haggart, 142 Mich App 330; 370 NW2d 345 (1985); People v Wesley, 103 Mich App 240; 303 NW2d 194 (1981); People v Cox, 85 Mich App 314; 271 NW2d 216 (1978).

trial court to ensure that the testimony was sufficiently reliable to sustain a verdict accepting the theory as factually probable.³²

This fundamental, mandatory gatekeeping obligation of the trial courts has been repeatedly and emphatically confirmed, not only in the prevailing authorities at the time of the trial in this matter, but also in the recent enactment of MCL 600.2955³³ and the amendment of

- (1) In an action for the death of a person or for injury to a person or property, a scientific opinion rendered by an otherwise qualified expert is not admissible unless the court determines that the opinion is reliable and will assist the trier of fact. In making that determination, the court shall examine the opinion and the basis for the opinion, which basis includes the facts, technique, methodology, and reasoning relied on by the expert, and shall consider all of the following factors:
- (a) Whether the opinion and its basis have been subjected to scientific testing and replication.
- (b) Whether the opinion and its basis have been subjected to peer review publication.
- (c) The existence and maintenance of generally accepted standards governing the application and interpretation of a methodology or technique and whether the opinion and its basis are consistent with those standards.
 - (d) The known or potential error rate of the opinion and its basis.

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These Michigan authorities are consistent with the federal authorities governing the gatekeeping responsibility of federal courts. See, e.g., <u>Daubert</u>, 509 US 579; <u>Kumho Tire Co, Ltd v Carmichael</u>, 526 US 137; 119 S Ct 1167; 143 L Ed 2d 238 (1999); <u>Dodge v Cotter Corp</u>, 328 F3d 1212 (CA 10, 2003); <u>Amorgianos v National R R Passenger Corp</u>, 303 F3d 256 (CA 2, 2002); <u>Mukhtar v California State University</u>, 299 F3d 1053 (CA 9, 2002), opinion amended 319 F3d 1073 (2003); <u>Nelson</u>, 243 F3d 244, 250; <u>Glastetter v Novartis Pharmaceuticals Corp</u>, 252 F3d 986 (CA 8, 2001); <u>Oddi v Ford Motor Co</u>, 234 F3d 136 (CA 3, 2000). Recently, as the Sixth Circuit explained in <u>Nelson</u>, FRE 702 was amended effective December 1, 2000, to incorporate the <u>Daubert standard</u>, which, in turn, is consistent with the gatekeeping requirement specifically set forth in <u>American Sterilizer</u>, in which the Michigan Court of Appeals specifically relied upon the <u>Daubert gatekeeping analysis</u>.

MCL 600.2955, which applies to actions filed on or after its effective date of March 28, 1996 (and which therefore does not technically apply here), provides in relevant part as follows:

MRE 702.³⁴ These amendments do not reflect a substantive change in the law. Rather, they were clearly inspired by the "generally recognized" fact that all too many, if not most, of the trial judges in this state have routinely failed to discharge their gatekeeping responsibility in accordance with longstanding authorities. At the time that this case was tried, those controlling authorities required the examination of the reliability of Plaintiff's proposed causation theory as conceived and presented by his experts. More specifically, the prevailing law at the time this matter was tried provided that: (1) the trial court was obliged to conduct an examination of the proposed expert testimony to determine whether it was sufficiently reliable so that it would assist, rather than mislead, the trier of fact; and (2) that the proponent of the expert's testimony, not the party challenging the testimony, has the burden of establishing its reliability and admissibility.

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(e) The degree to which the opinion and its basis are generally accepted within the relevant expert community. As used in this subdivision, "relevant expert community" means individuals who are knowledgeable in the field of study and are gainfully employed applying that knowledge on the free market.

- (f) Whether the basis for the opinion is reliable and whether experts in that field would rely on the same basis to reach the type of opinion being proffered.
- (g) Whether the opinion or methodology is relied upon by experts outside of the context of litigation.
- (2) A novel methodology or form of scientific evidence may be admitted into evidence only if its proponent establishes that it has achieved general scientific acceptance among impartial and disinterested experts in the field.

If the court determines that scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

³⁴ Effective January 1, 2004, MRE 702 now provides:

These fundamental gatekeeping requirements have long been the rule of law in Michigan. For example, in Young, 418 Mich at 21 n 7, this Court reversed a Court of Appeals decision that had improperly imposed the burden of proving the **unreliability** of expert testimony on the party challenging the testimony:

The Court of Appeals observed: "We conclude that because, in the present case, defendant offered no evidence that the electrophoresis technique used to compare the blood samples was scientifically inaccurate and because the defendant has not convinced us that the accuracy of electrophoresis is seriously disputed the trial court did not abuse its discretion in admitting Mark Stolorow's testimony without first requiring that the *Davis-Frye* standard be met." This is patently incorrect. The people were the offering party in this case. As the previously recited line of unanimous precedent unequivocally demonstrates, the party offering novel scientific evidence has the burden of demonstrating general scientific acceptance for reliability among impartial and disinterested experts before the evidence may be admitted. [Emphasis added.]

Subsequent decisions from the Court of Appeals have followed the mandate of <u>Young</u>. For example, in <u>Tobin</u> v <u>Providence Hospital</u>, 244 Mich App 626, 651; 624 NW2d 548 (2001), the Court of Appeals held that the plaintiff's expert's testimony that a detectable color change would occur in a bag of blood contaminated by the Yersinia bacterium was improperly admitted at trial because the expert's testimony "did not establish the evidentiary reliability and trustworthiness of

the trial courts should discharge their gate-keeping responsibility in accordance with MRE 702 and the abundant and longstanding <u>Davis-Frye</u> authorities.³⁵ Indeed, the gatekeeping requirements provided in <u>American Sterilizer</u> are consistent with not only the authorities that predate this decision, but also with the recent statutory (MCL 600.2955) and rule amendments.

The plaintiff in American Sterilizer claimed that she suffered injuries from exposure to ethylene oxide (EtO), a chemical used for sterilizing medical equipment. American Sterilizer, 233 Mich App at 487. At trial, two medical experts testified that they performed a "differential diagnosis" of the plaintiff's condition and determined that it was caused by EtO exposure. Id. at 488. The defendants challenged the expert's opinions under MRE 702 and the trial court then exercised its gate-keeping responsibility and held a hearing to examine the reliability of the experts' opinions. Id. at 487. Finding that, "Plaintiff had not shown that the expert's opinions were recognized by the scientific community," the trial court excluded the opinions. Id. In its initial decision, the Court of Appeals reversed, but after this Court vacated the opinion and directed the lower court to determine the admissibility of the expert opinions in accordance with MRE 702, the Court of Appeals affirmed the findings of the trial court that the experts' opinions lacked the requisite objective scientific validation. Id.

In <u>American Sterilizer</u>, the Court of Appeals characterized the trial court's responsibility to scrutinize expert opinion this way:

The question . . . is scientific in nature, and it is to the scientific community that the law must look for the answer. For this reason, expert witnesses are indispensable in this case. But that is not to say that the trial court's hands were inexorably tied, or that it must have accepted uncritically any sort of opinion espoused by either party's proffered experts merely because their credentials rendered them qualified to testify. **To the contrary, under the rules of evidence, the trial court was charged with**

In <u>Young</u>, 418 Mich at 24, this Court explained that "[t]he <u>Davis-Frye</u> standard is the means by which the court can determine that the novel evidence offered for admission" is generally accepted as being reliable, and thus recognized, for purposes of MRE 702.

ensuring that any and all scientific testimony to be admitted was not only relevant, but also reliable." [Id. at 489 (emphasis added).]

The Court in American Sterilizer then explained how the judicial gate-keeper goes about the task of ensuring the reliability of expert testimony. First, the judge must determine whether there is objective, independent validation for the expert opinion; that is, the expert's opinion must be shown to be based upon something other than his credentials and his "say so." Second, the objective, independent validation must also be recognized in the relevant scientific community and reliable insofar as it was generated from the use of accepted methodology in the particular field. Third, to ensure reliability, the judge must determine whether the objective, independent foundation relied upon by the expert justifies the expert's conclusions. In the words of the Court of Appeals in American Sterilizer:

We conclude that MRE 702 requires a trial court to determine the evidentiary reliability or trustworthiness of the facts and data underlying an expert's testimony before that testimony may be admitted. To determine whether the requisite standard of reliability has been met, the court must determine whether the proposed testimony is derived from "recognized scientific knowledge." [Id. at 491.]

Proposed testimony is derived from "recognized scientific knowledge" (or, in the words of the new MRE 702 – proposed testimony is the product of "reliable principles and methods") only when it contains "inferences or assertions, the source of which rests in an application of scientific methods. Additionally, the inferences or assertions must be supported by appropriate objective and independent validation based on what is known, e.g., scientific and medical literature." <u>Id</u>. The Court in <u>American Sterilizer</u> clarified that it is not necessary "that the subject of the scientific testimony must be known to a certainty. **As long as the basic methodology and principles employed by an expert to reach a conclusion are sound and create a trustworthy foundation for the conclusion reached, the expert testimony is admissible no matter how novel." <u>Id</u>. at 491-492 (emphasis added).**

The requirement of objective, independent validation of the expert opinion, as described in <u>American Sterilizer</u>, derives from the "recognized knowledge standard" of MRE 702 as well as the analytical criteria of <u>Daubert</u>, now expressly incorporated into the revised MRE 702, which also requires the proposed testimony to be "the product of reliable principles and methods." In <u>Daubert</u>, the Ninth Circuit, on remand from the United States Supreme Court, elaborated on the importance of objective, independent validation:

The experts must explain precisely how they went about reaching their conclusions and point to some objective source—a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like—to show that they have followed the scientific method, as it is practiced by (at least) a recognized majority of scientists in their field.

<u>Daubert v Merrell Dow Pharmaceuticals (On Remand)</u>, 43 F3d 1311, 1319 (CA 9 1995) (<u>Daubert II</u>). In the absence of a showing that there is objective, independent of validation for the expert's opinion outside the courtroom, the scientific soundness of an expert's causation theory cannot be evaluated and that evidence should be excluded.

3. The Trial Court Here Failed to Discharge its Burden and Consider Defendant's Challenge to Dr. Gabriel's Novel, Unreliable, and Factually Unsupported Causation Theory

If the trial court and Court of Appeals had followed the requirements of MRE 702 and the controlling case authorities, Defendants' challenge to the causation theory that Dr. Gabriel formulated should have led to the exclusion of his testimony and the dismissal of this case. Clearly, the trial court's failure to follow the law and even consider the lack of independent, objective validation for Dr. Gabriel's theory, the lack of support in the factual record for both experts' testimony, and the material inconsistencies between the experts' testimony and the

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³⁶ Consequently, although the new MRE 702 eliminates the term "recognized," the concept is still embodied in the express requirement of the rule that an expert's testimony be "the product of reliable principles and methods."

record facts led to an unjust, catastrophic verdict based on speculation, not on evidence. In failing to correct the trial court's error and the injustice it wrought, the Court of Appeals compounded both the legal error and the injustice by adopting a new and broadly consequential rule of law that departs from longstanding authority and from the current mandate of this Court and the Legislature.

As the controlling authorities made clear at the time this case was tried, Defendants had no greater "burden" than to bring to the trial court's attention their challenge to the reliability of Dr. Gabriel's "pounding and grinding" theory of fetal brain injury. Defendants here did this and more. Defendants presented the sworn testimony of Dr. Gabriel, in which he acknowledged he could offer no medical or scientific literature of any kind even to support his theory as a possible cause of fetal brain injury. At that juncture, the trial court was obliged by law to evaluate the reliability of Dr. Gabriel's theory and to determine whether the theory could be objectively validated outside the courtroom and substantially supported by the admissible factual record. Both the trial court and the Court of Appeals abdicated their fundamental gatekeeping responsibility to ensure that only reliable evidence reaches the jury so that the verdict will be fairly and reliably based on facts, not on theory, or worse, on sheer contrivance.

a) The Lack of Objective, Independent Validation For Dr. Gabriel's Theory

Dr. Gabriel vaguely alluded in his deposition and at trial to studies "in the 50's and 60's" that support his causation theory, but he was never able even to provide one citation to any medical or scientific literature and he attempted to end any further inquiry into the lack of objective, independent validation for his theory by acknowledging that "[t]raumatic head injuries have essentially disappeared in obstetrical practice in the United States." (Deposition of Dr. Ronald Gabriel: 123a-128a; Dr. Gabriel's trial testimony: 241a). Further, Dr. Gabriel's confusing references at trial to "monkey studies" on the general effects of Pitocin (238a-240a) do

not qualify as objective, independent validation because he was unable to offer citations to such studies and he could not even explain how such studies supported his "pounding and grinding" theory of fetal brain injury.

As <u>American Sterilizer</u> instructs, the gate-keeping analysis under MRE 702 does not end even when the expert is able to cite to peer-reviewed literature to support his theory. The trial court must examine the literature cited by the expert to determine whether it supports his conclusions. For example, the trial court and the Court of Appeals in <u>American Sterilizer</u> found that the animal studies cited as support for the plaintiffs' experts' opinion did not provide the requisite reliability for the application of the opinion to humans.³⁷ Both the trial court and the Court of Appeals reasoned that the <u>general</u> causation question at issue in <u>American Sterilizer</u> – *does low level chronic exposure to EtO cause liver disease in humans*? — was not reliably answered by the animal studies the experts cited. Plainly, Dr. Gabriel's vague allusion to some literature many decades ago and "monkey studies" that he could not cite does not provide the objective, independent validation for his theory that is required to ensure its reliability. In this case Dr. Gabriel was not even able to reach the first step in the required reliability examination; he could not provide objective validation of **general causation**, e.g., "pounding and grinding" of the fetal head against a pelvic structure **can cause** brain injury.

b) The Lack of Any Reliable Methodology by Which Dr. Gabriel Reached His Conclusions

Dr. Gabriel's "pounding and grinding" theory is not founded in a reasoned application of scientific methods or differential clinical analysis. Rather, it was essentially Dr. Gabriel's

The court did not find it necessary to decide the question of whether expert opinion may ever be based entirely on animal studies, but suggested serious doubt about the reliability of such studies as exclusive support for opinions as to causation in humans. <u>American Sterilizer</u>, 223 Mich App at 495.

conclusion that Antonio Craig's injury must have been caused by some unusual event during labor and delivery because Dr. Gabriel could not trace the injury to any of the several *generally* recognized causes of fetal brain injury. (See Deposition of Dr. Ronald Gabriel [109a]).

The fundamental logical problem with Dr. Gabriel's "methodology" and "analysis" is also anathema to proper clinical and scientific reasoning. The ruling out of other known causes does not "rule in" the medically unprecedented head trauma scenario that Dr. Gabriel advanced as causation evidence to a jury. As Dr. Gabriel himself admitted, he lacks competence even to discuss pelvic anatomy, let alone the mechanism by which Antonio Craig's head and brain could have been traumatized by the "pounding and grinding" scenario:

- Q. Can you tell me, Doctor, what portions of the fetal head were actually touching the pelvis?
- A. I cannot visualize given his reported position and the anatomy of the pelvis, because it's outside of my area of knowledge. [112a-113a]

* * *

- Q. Doctor, can you explain to the jury, how the head was either being crushed against the pelvis, pounded against the pelvis, grounded against the pelvis during uterine contractions but at the same token how or why it would be able to rotate through pelvis for normal delivery?
- A. That's an obstetrical question and I don't think I'm competent to answer that in terms of the anatomy. [251a-252a]

Dr. Gabriel's analysis and methodology amount to nothing more than illogic and speculation. In <u>Black v Food Lion, Inc</u>, 171 F 3d 308, 313 (CA 5, 1999), the Fifth Circuit rejected a similar analytical methodology. The plaintiff's expert in <u>Black</u> posited that the plaintiff's fibromyalgia had to have been caused by a slip-and-fall because the expert thought she had eliminated other causes, despite the fact that no studies supported the expert's theory that trauma can cause fibromyalgia. As the court in <u>Black</u> explained: "This is not an exercise in scientific logic but in the fallacy of *post-hoc propter-hoc* reasoning, which is unacceptable in science as in law."

4. As a Matter of Sound Policy, the Judge, Not the Jury, Must Assume the Role of Gate-keeper in Order to Ensure That Verdicts are Based on Evidence and Not on Experts' Speculation

Presenting the opinion of a medical expert sends the simple but powerful message that the opinion must at least enjoy some support in medical science. The expert's appearance on the stand is a communication to the jury that his or her opinions are entitled to be treated as evidence because, based on the expert's specialized knowledge, he must be better equipped than the jury to interpret the facts and answer the same dispositive questions of causation that the jury will ultimately be called upon to answer.

However, when the expert's opinion cannot be shown to be based on objective independent evidence generally recognized in the relevant community, then the opinion is nothing more than speculation cloaked in impressive credentials. As such, it is not only unhelpful to the jury in evaluating the medical facts, it actually diverts the jury's focus from an assessment of the established medical facts. As the Court observed in <u>Porter v Whitehall Laboratories</u>, Inc., 791 F Supp 1335, 1345 (SD Ind 1992):

...[T]here is a risk that the jury would make an irrational finding of causation based upon the siren-like allure of opinions stated by highly qualified experts. Thus, an expert's opinion must have <u>some</u> basis other than hypothesis before the opinion may have the privilege of being assailed by cross-examination.

By the time an expert's opinion passes through the judicial gateway and demands the jury's deference, the risk of a verdict based upon scientifically unsound assumptions cannot be adequately reduced by even the most vigorous cross examination. This is why the judge, not the jury, must be the gate-keeper, probing carefully and critically the foundational underpinning of expert testimony to assure that theory and conjecture are not presented to the jury in the guise of legitimate, scientifically sound opinion.

This trial record reveals that Plaintiff's entire case was balanced on a causation theory of

experts willing to invent what medical science and the established facts of this case cannot

explain. Indeed, as explained by defense expert neurologist, Dr. Michael Nigro, and defense

expert neonatologist, Dr. Steven Donn, it simply is inconceivable that the brain impairment with

which Antonio Craig was diagnosed at age one was caused by a birth trauma. (See 410a-415a;

421a-425a). Had the trial court conducted a proper Davis-Frye/MRE 702 hearing, it would have

discovered what the five-week trial record makes painfully clear: the causation theory that

Plaintiff's experts hoped a jury would accept is not even recognized outside a courtroom as

anatomically possible and is in conflict with the established facts. Plaintiff's case should have

been dismissed before trial.

CONCLUSION AND REQUESTED RELIEF IV.

For all of the reasons stated, Oakwood respectfully requests that this Court reverse the

Court of Appeals' opinion, vacate the judgment entered against Oakwood, and remand this

matter to the trial court for entry of judgment NOV in Oakwood's favor. In the alternative, and

at the very least, Oakwood asks this Court to order a new trial.

Respectfully Submitted,

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